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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,985	03/19/2004	Sylvia Daunert	50229-430	6910

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McDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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08/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,985	Applicant(s) DAUNERT ET AL.	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-15,17,19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7 is/are allowed.
- 6) ☒ Claim(s) 9-15,17,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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CLAIMS 1-7, 9-15, 17, 19 AND 20 ARE PRESENTED FOR EXAMINATION

Applicants' compliant amendment filed May 2, 2008 has been received and entered into the application. Accordingly, claims 3, 14 and 15 have been amended and claims 8, 16 and 18 have been deleted. The rejections not reiterated from the previous Office action not presented herein are deemed overcome.

The following Office action presents all issues present.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims Allowable

Claims 1-7 are in condition for allowance for the reasons set forth in the previous Office action at page 2, as applied to claims 1, 2, 6 and 7, under the heading "***Claims Allowable***"

Claim Objection

In light of Applicants' amendment, i.e., claim 4 now dependent on allowable claim 3, the objection to claims 4-5, as set forth in the previous Office action dated January 25, 2008 at page

3, has been overcome and thus is now withdrawn. Claims 4-5 are now in condition for allowance.

Claim Rejection - 35 USC § 112, First Paragraph

Claims 9, 10, 12-15, 17, 19 and 20 remain rejected under 35 U.S.C. 112, first paragraph, , because the specification, while being enabling for a drug delivery device for controlled delivery of a therapeutic or diagnostic agent or for a method for delivering a therapeutic or diagnostic

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agent, does not reasonably provide enablement for a drug delivery device comprising, or a method for delivering a prophylactic agent.

This rejection is maintain for the reasons set forth in the previous Office action dated January 25, 2008 at pages 3-6, which reasons are herein incorporated by reference.

In said rejection, the Examiner, as per the Court's guidance in *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (CCPA 1971), set forth a valid reason for doubting Applicants' contention that an agent, which acts as a prophylactic agent, could be present or delivered, as per the present claims.

In response to such rejection, and rather than directly refuting the Examiner's and Court's opinion, Applicants have chosen to provide a dictionary definition for the term "prophylactic" which is not as stringent as the Examiner's interpretation where the drug or agent provides an action such that the disease/disorder fails to manifest itself in any manner.

Applicants' attempt to overcome the present rejection is not persuasive because, as set forth in the previous Office action, the Examiner is directed and required, as per the Court and MPEP § 2111, to give a claim term its broadest and reasonable interpretation. The Examiner, in stark contrast to Applicants, has met this burden and Applicants' reference to Websters New World Dictionary Third College Edition fails to diminish the propriety of the Examiner's interpretation that the term "prophylactic" which is reasonable and more stringent than Applicants' interpretation, whether supported by a reference or not. In particular, nothing presented by Applicants addresses the Examiner's interpretation in any manner, much less refuting it.

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Accordingly, the Examiner will maintain this rejection as being proper and believes this rejection in condition for decision on appeal by the Board of U.S. Patent Appeal and Interference.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
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August 17, 2008